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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,827	10/10/2006	Masahiro Yamauchi	2006_1488A	4401

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EXAMINER	
EPPS -SMITH, JANET L	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
12/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,827	YAMAUCHI ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39,40,42 and 48-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39,40,42 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09-06-06; 02-22-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Group I-III drawn to claims 1-38, 41 and 43-47 were cancelled by Applicants. Claims 39-40, 42 and 48-50 are pending for examination.

Election/Restrictions

2. Applicant's election of Group V claims 39-42 in the reply filed on 9/18/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 39-40, 42, and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al. (US20040022938).

5. The instant claims are drawn to a method for producing coated complex particles comprising the steps of:

dispersing or dissolving a nucleic acid and an anionic polymer in a liquid with lead particles, wherein the lead particles comprise a lipid assembly, a liposome, an emulsion particle or a polymeric micelle, containing

(i) one or more substance(s) selected from polyethylene glycolated lipids, polyethylene glycol sorbitan fatty acid esters, polyethylene glycol fatty acid esters,

polvglycerolated lipids, polvglycerol fatty acid esters, po!yoxyethvlene polypropylene glycol, glycerol fatty acid esters and polyethylene glycol alky1 ethers, and

(ii) a catonic substance,

wherein the nucleic acid and the anionic polymer adhere to the lead particles to obtain complex particles;

preparing a liquid (liquid A)containing a polar organic solvent in which obtained complex particles are dispersed and a lipid membrane component is dissolved; and coating the complex particles with a lipid membrane composed of the lipid membrane component by reducing the ratio of the polar organic solvent in the liquid A.

Kato et al. teach a method for coating fine particles, see the following disclosure at paragraphs [0008]-[0009]: a method for coating fine particles with lipid membrane, which comprises coating fine particles with lipid membrane by decreasing the concentration of a polar organic solvent in an aqueous solution containing the polar organic solvent where the fine particles are dispersed and lipid is dissolved. The method is also described as follows: a method for coating fine particles with lipid membrane, which comprises coating fine particles with lipid membrane by dispersing fine particles in an aqueous solution containing a polar organic solvent (liquid A), dissolving lipid in a polar organic solvent or an aqueous solution containing a polar organic solvent which is the same as or different from the above aqueous solution containing a polar organic solvent (liquid B), mixing the liquid A and the liquid B into liquid C, and decreasing the concentration of a polar organic solvent in the liquid C to

obtain liquid D. Kato et al. also disclose wherein said method comprises the following embodiments, see ¶'s [0010]-[0013] (3) The method for coating fine particles with lipid membrane according to the above (2), wherein the liquid B is a solution which is prepared by dissolving a water-soluble polymer derivative (I) together with the lipid. (4) The method for coating fine particles with lipid membrane according to the above (2) or (3), wherein the concentrations of the polar organic solvent in the liquid A and the liquid B are 30% or more. (5) The method for coating fine particles with lipid membrane according to the above (2) or (3), wherein the concentrations of the polar organic solvent in the liquid A and the liquid B are 60 to 90%. (6) The method for coating fine particles with lipid membrane according to the above (5), wherein the concentration of the polar organic solvent in the liquid D is 50% or less.

Paragraphs [0014]-[0015] teach the following: (7) The method for coating fine particles with lipid membrane according to any one of the above (1) to (6), wherein the fine particles are those containing a water-soluble polymer derivative which is the same as or different from the water-soluble polymer derivative (I) recited in the above (3). (8) The method for coating fine particles with lipid membrane according to any one of the above (1) to (7), wherein the fine particles are those containing one or more member(s) selected from a drug, lipid assembly, liposome, fine particles in the emulsion, natural polymer, synthetic polymer, metal colloid, cationic lipid, anionic lipid and a fine particle preparation.

The method of Kato et al. also comprise wherein the fine particles comprise a complex of a drug with one or more member(s) selected from lipid assembly, liposome,

fine particles in the emulsion, natural polymer, synthetic polymer, metal colloid, cationic lipid, anionic lipid and a fine particle preparation (see ¶ [0017]). The method also comprises wherein the fine particle comprises a complex of a drug with anionic lipid, see ¶ [0019], and further wherein said drug is a nucleic acid, see ¶ [0021]. The method further comprises wherein the fine particles comprise a complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt, see ¶ [0020]. The polar organic solvent used in the methods of Kato et al. include one or more member(s) selected from an alcohol, a glycol and a polyalkylene glycol; wherein the alcohol is ethanol; wherein the glycol is a propylene glycol; wherein the polyalkylene glycol is polyethylene glycol, see paragraphs [0022-0025].

Kato et al. discloses wherein the fine particles are those containing a water-soluble polymer, and further wherein said water-soluble polymer derivative is one or more member(s) selected from polyethylene glycolated lipid, a polyethylene glycol alkyl ether, a polyethylene glycol castor oil derivative, a polyethylene glycol sorbitan fatty acid ester, a polyethylene glycol stearate, a copolymer of ethylene glycol with propylene glycol and a glycerol ester, see ¶ [0026].

Examples of the polar organic solvent in the aqueous solution containing the polar organic solvent used in the Kato et al. methods are an alcohol such as methanol, ethanol, n-propanol, isopropanol, n-butanol, isobutanol and tert-butanol; a glycol such as glycerol, ethylene glycol and propylene glycol; and polyalkylene glycol such as polyethylene glycol.

Further embodiments of the methods of Kato et al. include the following, see paragraphs [0028]-[0030]:

[0028] With regard to the thing which constitutes the fine particles used in the present invention, there is no particular limitation and its examples are a drug, lipid assembly, liposome, fine particles in emulsion, natural polymer, synthetic polymer, metal colloid, cationic lipid, anionic lipid, a fine particle preparation and a water-soluble polymer derivative. They may be used independently, as a complex where two or more of them are combined, or as a complex where one or more of them and another compound are combined. To be specific, an example of the above-mentioned complex is a complex of drug with one or more member(s) selected from lipid assembly, liposome, fine particles in emulsion, natural polymer, synthetic polymer, metal colloid, cationic lipid, anionic lipid and a fine particle preparation. With regard to the drug, its examples are substances having a pharmacological activity such as a protein including enzyme, a peptide, a nucleic acid including gene, a low-molecular compound, a saccharide and a polymer compound.

Kato et al. clearly reads on the limitations of the claimed invention particularly to the extent that it discloses a method for producing coated complex particles, wherein the particle comprises a complex of a drug with anionic lipid, see ¶ [0019], and further wherein said drug is a nucleic acid, see ¶ [0021]. The fine particles of Kato et al. further comprise wherein the fine particles are those containing one or more member(s) selected from a drug, lipid assembly, liposome, fine particles in the emulsion, natural polymer, synthetic polymer, metal colloid, cationic lipid, anionic lipid and a fine particle

preparation, see paragraphs [0014]-[0015]. The method further comprises wherein the fine particles comprise a complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt, see ¶ [0020]. The polar organic solvent used in the methods of Kato et al. include one or more member(s) selected from an alcohol, a glycol and a polyalkylene glycol; wherein the alcohol is ethanol; wherein the glycol is a propylene glycol; wherein the polyalkylene glycol is polyethylene glycol, see paragraphs [0022-0025].

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633